

MAY 27 1999

K990753

VII.1

**510(k) Premarket Notification  
HDR Applicator Catheter  
COOK INCORPORATED**

## **APPENDIX VII**

### **SMDA SUMMARY**

510(k) Premarket Notification  
HDR Applicator Catheter  
COOK INCORPORATED

### **Safety and Effectiveness Information**

**Submitted By:** April Lavender, RAC  
Vice President, Regulatory Affairs  
COOK INCORPORATED  
925 South Curry Pike  
P.O. Box 489  
Bloomington, IN 47402  
(812) 339-2235

**Device:** Trade Name: GRAC High Dose Rate (HDR) Remote  
Afterloading Catheter

Proposed Classification Name: Remote Controlled Radionuclide Applicator  
System

### **Intended Use:**

The GRAC High Dose Rate (HDR) Remote Afterloading Catheter is intended for remote afterloading of a radiation source. To be used with the GammaMed 12i Remote High Dose Rate Afterloader system, supplied by Frank Barker Associates of Tuwaco, New Jersey.

### **Predicate Devices:**

The GRAC High Dose Rate (HDR) Remote Afterloading Catheter is similar in terms of intended use, materials of construction, and technological characteristics to predicate devices reviewed as remote afterloading catheters.

### **Device Description**

The GRAC High Dose Rate (HDR) Remote Afterloading Catheter is a 5.6 French , 129cm long, single lumen catheter. The distal end of the catheter is closed. The outside diameter of the shaft has placement markings to facilitate accurate pre-treatment positioning of the catheter. The catheter is compatible with the GammaMed 12i Remote High Dose Rate Afterloader supplied by Frank Barker Associates, of Tuwaco, New Jersey.

### **Substantial Equivalence**

The GRAC High Dose Rate (HDR) Remote Afterloading Catheter is similar to other Cook Incorporated remote afterloading catheters which were found substantially equivalent under

**510(k) Premarket Notification**  
**HDR Applicator Catheter**  
**COOK INCORPORATED**

510(k) #D.C. K945383 and D.C. K981886. The similar indications for use and technological characteristics of the GRAC High Dose Rate (HDR) Remote Afterloading Catheter as compared to the predicate devices supports a determination of substantial equivalency.

**Test Data**

The GRAC High Dose Rate (HDR) Remote Afterloading Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- ❖ Internal Friction Force
- ❖ Radiation Exposure
- ❖ Leak Test
- ❖ Tensile Strength
- ❖ Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a remote controlled radionuclide applicator.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 27 1999

April Lavender  
Vice President, Regulatory Affairs  
Cook, Inc.  
925 South Curry Pike  
Bloomington, IN 47402

Re: K990753  
GRAC High Dose Rate (HDR)  
Remote Afterloading Catheter  
Dated: March 4, 1999  
Received: March 8, 1999  
Regulatory class: II  
21 CFR 892.5700/Procode: 90 JAQ

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Premarket Notification  
HDR Applicator Catheter  
COOK INCORPORATED

510(k) Number (if known): K 9 9 0 7 5 3

Device Name: High Dose Rate (HDR) Remote Afterloading Catheter

Indications for Use:

Used for remote afterloading of a radiation source. To be used with the GammaMed 12i Remote High Dose Rate Afterloader system, supplied by Frank Barker Associates of Tuwaco, New Jersey.

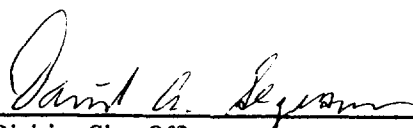
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990753